

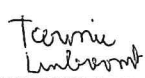


# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title:</b> Cetostearyl Alcohol BP (Item No. 41020680)	<b>Spec. No. :</b> SP-AK30-C41
<b>Reference(s):</b> BP 2020 page I-512 to I-513	<b>Rev. No. :</b> 04
<b>Other Requirements: -</b>	<b>Page :</b> 1/2

### BP 2020

Test Parameters	Requirement
Description	White or pale yellow, wax-like mass, plates, flakes or granules.
Solubility	Practically insoluble in water, soluble in ethanol (96 per cent) and in light petroleum.
Identification	Examine the chromatograms obtained in the assay. The 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time to the principal peaks in the chromatogram obtained with the reference solution.
Appearance of solution	The solution is clear and not more intensely coloured than reference solution B <sub>6</sub> .
Melting point	49 °C – 56 °C.
Acid value	Not more than 1.0.
Hydroxyl value	208 – 228.
Iodine value	Not more than 2.0.
Saponification value	Not more than 2.0.
Assay	Stearyl alcohol : Not less than 40.0%.
	Sum of the contents of stearyl alcohol and cetyl alcohol : Not less than 90.0%.

<b>Prepared by:</b> J. Noppadech / 02/09/20 Head of Raw Material Standard Section 2	<b>Reviewed by:</b> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">             Director of Raw Material            Standard Division         </div> <div style="text-align: center;">             Director of Drug Registration and            Pharmacovigilance Division         </div> </div>	<b>Approved by:</b> <div style="text-align: center;">             Director of Quality Assurance            Department (A)         </div>	<b>Eff. Date</b> 15/09/20
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### Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Cetostearyl Alcohol (Item No. 41020680).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C41.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective Date
03	Update ข้อกำหนดตาม BP 2013	19/09/14
04	Update ข้อกำหนดตาม BP 2020	15/09/20

Prepared by:  J. Noppadech / 02/09/20 Head of Raw Material Standard Section 2	Reviewed by: Tarnie Lunlomb , 03/09/20 Director of Raw Material Standard Division	Approved by: Wichien Rungnongroj , 09/09/20 Director of Quality Assurance Department Achin	Eff. Date  15/09/20
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